DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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June 24, 2005 (REVISED)

WARNING LETTER NO. 2005-NOL-25

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Ms. Ta Taponpanh, Owner
Chan Ta Seafood
14580A Saint Michael Road
Coden, Alabama 36523

Dear Ms. Taponpanh:

On April 11, 13 - 14, 2005, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, located at 14580A Saint Michael Road, Coden, Alabama. We found you have serious deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, *Code of Federal Regulations*, Parts 110 and 123 (21 CFR 110). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan to comply with this section or otherwise operate in accordance with requirements of this part, renders the fishery products adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 USC, Section 342(a)(4). You may find the Act and the Seafood HACCP regulation through links in FDA's home page at www.fda.gov. Accordingly, your ready-to-eat crabmeat is adulterated, because it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

During the inspection, our investigators collected samples of your cooked, ready-to-eat crabmeat. The samples were subsequently analyzed for the presence of microorganisms. You should be aware *Listeria monocytogenes* (*L. monocytogenes*) was recovered from one sample, collected on April 11, 2005. *L. monocytogenes* in your ready-to-eat crabmeat causes your crabmeat to be in violation of Section 402(a)(1) of the Act, 21 USC, Section 342(a)(1), as it contains a poisonous and deleterious substance, evidenced by FDA's isolation of *L. monocytogenes* in the crabmeat, which was processed and packed by your firm.

Listeria monocytogenes is a pathogenic microorganism, which can cause the serious food-borne bacterial illness known as "listeriosis." Listeriosis can be a serious illness for some people, especially the elderly, newborns, pregnant women and those with weakened immune systems. This bacteria is widely present in the environment. Food processors and handlers should take all precautions necessary to reduce the risk of contamination and to keep food safe from *L. monocytogenes*. Since *L. monocytogenes* is such a difficult microorganism to control, you may want to consider referring to the expertise of a consultant to control and eliminate this pathogen

from your processing facility and products. We strongly recommend you determine the cause(s) of this problem and take corrective action as soon as possible. Strict sanitation measures must be instituted to prevent the presence of this microorganism in your finished product.

The deviations were as follows:

1. You must implement the monitoring procedures and associated recordkeeping systems listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, you did not follow your procedure of monitoring: (a) the time and temperature of handling cooked crabs during the "Backing" critical control point (CCP); or, (b) the temperature of cooked crabs during the "Backed crab and claw cooling," "Backed crab and claw cooler," "Picking and packing," and "Finished product storage" CCPs to control pathogen growth and toxin formation listed in your HACCP plan for fresh, picked crabmeat.

   You did not record monitoring observations at the "Backing," "Backed crab and claw cooling," "Backed crab and claw cooler," "Picking and packing," and "Finished product storage" CCPs to control pathogen growth and toxin formation listed in your HACCP plan for fresh, picked crabmeat. Monitoring records, associated with the above-listed CCPs, were unavailable for October 1, 2004 through March 6, 2005, and March 29, 2005 through April 8, 2005.

2. You must fully document all corrective actions taken, to comply with 21 CFR 123.7(d). However, when your process for cooked crabmeat deviated from your critical limit at the "Cooking" CCP, you failed to document a corrective action was taken to ensure the affected product was segregated; a review of the affected product was conducted to determine its acceptability; the affected product was not entered into commerce; and, the cause of the deviation was corrected.

   Specifically, your HACCP plan for fresh, picked crabmeat requires at the "Cooking" CCP a critical limit of boiling at a rolling boil for 15 minutes. When the cook process deviates from the critical limit, corrective actions, required by your HACCP plan, include re-cooking the crabs and/or segregating and holding the crabs for evaluation. The following cooking processes were logged with cook times less than 15 minutes and without documentation associated corrective action was taken: cook #1, dated February 6, 2005; cook #8, dated January 6, 2005; cook #3, dated October 26, 2004; cook #5, dated October 25, 2004; and, cook #2, dated October 21, 2004.

3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). Your firm did not monitor the safety of water coming into contact with food or food contact surfaces; the condition and cleanliness of food contact surfaces; the prevention of cross-contamination from insanitary objects; the maintenance of hand washing, hand sanitizing, and toilet facilities; the protection of food, food packaging material, and food contact surfaces from adulteration; the proper labeling, storage, and use of toxic chemicals; and, the exclusion of pests as evidenced by the following observations.

   On April 13, 2005, our investigators observed:

a. Cook employees routinely conducting tasks, such as emptying crab waste containers, shoveling cooked crab parts, stacking crates and pallets, and handling live crabs, then touching backed crabs and backed crab contact surfaces without washing or sanitizing their hands;

b. Employees washing perforated baskets and the floor with well water. While washing the floor, the well water was observed splashing on several cooked crab contact surfaces, including employees' gloves, aprons, and a cooking basket. You were unable to provide our investigators documentation on the safety of well water used in your facility;

c. Cook employees routinely handled an unsanitized, rusty hoist chain. The same employees then handled cooked crabs without sanitizing their hands or gloves;

d. Numerous live, gnat-type insects present in the cooking/backing room during processing;

e. Live, gnat-type insects contacting cooked crabs, cooked crab contact surfaces, and ice used to cool cooked crabs and cooked crab parts;

f. Gnat-type insects and insect parts on cooked crabmeat, cooked crab holding, backing, picking, and packing tables, picking bowls, crabmeat cups and lids, ice used to cool cooked crabs, picking knives, gloves, and an apron;

g. An employee's shirt sleeve routinely contacting cooked crabs and cooked crab contact surfaces;

h. Two cans of pest control spray stored adjacent to finished product packing material;

i. During backing of cooked crabs, employees routinely using three metal rakes with open-ended handles to move cooked crabs. The open-ended handles of the rakes did not allow for proper washing or sanitizing of the rakes; and,

j. Two employees not wearing proper hair restraints while standing over backed and cooked crabs.

On April 14, 2005, our investigators observed another employee not wearing proper hair restraints while standing over open containers of cooked crabmeat and cooked crabs.

Throughout the inspection, our investigators observed three light fixtures without protective coverings suspended over exposed cooked crabmeat.

Lastly, although not documented on the Form FDA 483, our investigators discussed with you, your chlorine-based sanitizing solution, used to sanitize processing equipment and employees' hands and gloves, was below the required 100 parts per million strength.

4. You must maintain sanitation control records, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). However, you did not maintain sanitation

monitoring records required for processing cooked, ready-to-eat crabmeat from October 1, 2004 through April 14, 2005.

5. You must manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contaminants, to comply with 21 CFR 110.80(b)(2). You were unable to provide our investigators any documentation affirming the safety of well water used in your facility from October 1, 2004 to April 13, 2005. As stated above, on April 13, 2005, our investigators observed employees washing perforated baskets and flooring with well water. While washing the floor, the well water was observed splashing on several cooked crab contact surfaces, including employees' gloves, aprons, and a cooking basket.

6. In accordance with 21 CFR 123.9(a), all records required by your HACCP plan shall include: the date and time of the activity the record reflects; the signature or initials of the person performing the operation; and, where appropriate, the identity of the product and the production code, if any. All processing or other information must be entered concurrent with the activity or when the observation was made. Your firm also failed to comply with 21 CFR 123.8(a)(c) because you did not review your CCP monitoring records within one week of the day the records were made.

Our investigators also informed you during the inspection your facility is subject to the registration requirement in Section 415 of the Act, 21 USC, Section 350(d), and our implementing regulation at 21 CFR 1, Subpart H, Sections 1.225 - 1.243. The failure to register a facility as required is a prohibited act under Section 301 of the Act, 21 USC, Section 331. Registration of your firm may be accomplished on-line at http://www.access.fda.gov. We strongly encourage the use of electronic registration because it will result in an automatic confirmation of registration and automatic issuance of a registration number. Alternatively, you may register your firm by mail or fax using FDA's food facility registration form, Form 3537, which is enclosed. When completed, you may fax the form to (301) 210-0247 or mail it to:

U.S. Food and Drug Administration, HFS-681
5600 Fishers Lane
Rockville, MD 20857

Please respond in writing within fifteen (15) working days from your receipt of this letter outlining the specific steps you are taking to correct the deviations, including an explanation of each step taken to prevent recurrence of similar violations. You should include in your response documentation, such as a revision of your seafood HACCP plan, sanitation control records, corrective action records, or other useful information to assist us in evaluating your corrections. If you cannot complete all corrections within 15 working days, we expect you to explain the reason for your delay and state when you will correct any remaining deviations.

We are aware you made promises to correct the observed deficiencies. You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action, including seizure and/or injunction, without further notice.

This letter is not intended to be an all-inclusive list of the deviations at your facility. You are responsible for ensuring your facility operates in compliance with the Act, Seafood HACCP

regulation, and Current Good Manufacturing Practice regulation (21 CFR 110). You also have a responsibility to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District

Enclosures: Forms FDA 483 & 3537
21 CFR 110 and 123